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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,671	11/09/2005	Hideaki Yamaoka	TOYA114.007APC	1379
20995 7590 06/01/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER LONG, SCOTT	
			ART UNIT 1633	PAPER NUMBER
			NOTIFICATION DATE 06/01/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/550,671

Applicant(s)

YAMAOKA ET AL.

Examiner

Scott D. Long

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9/26/2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/2005 & 7/2006
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Status

Claims 1-9 are pending. Claims 1-9 are under current examination.

Sequence Compliance

Sequence Listing and CRF have been received and are acknowledged by examiner. A statement that the Computer Readable Form (CRF) and the Sequence Listing are identical has been submitted and is acknowledged by examiner.

Oath/Declaration

The oath or declaration, having the signatures of all inventors, received on 9 November 2005 is in compliance with 37 CFR 1.63.

Information Disclosure Statement

The Information Disclosure Statements (IDS) filed on 11 May 2006 consisting of 3 sheets are in compliance with 37 CFR 1.97. Accordingly, examiner has considered the Information Disclosure Statements.

Priority

This application claims benefit as a 371 of PCT/JP04/04074 (filed 03/24/2004).
This application claims benefit from foreign application JAPAN 2003-082739 (filed

03/25/2003). Because the English translation of JAPAN 2003-082739 was not provided, the instant application has been granted the benefit date, 24 March 2004, from PCT/JP04/04074.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected because the term, "ccm" is not clear. This acronym is not elaborated in the claim, and thus, the metes and bounds of the claims are unclear. Clarification of this term is required.

Claim 1 is rejected because the term, "in an expressible form" is not clear. What exactly does this mean? Is it the arrangement of the subunits on the DNA that makes them expressible? Or are there inexpressible forms of the subunits, perhaps mutant forms? Or does this refer to an expressible form of the assembled multimeric glucose dehydrogenase? In any case, the meaning of this phrase is unclear.

Claim 1 recites the phrase "the α -subunit and the β -subunit" in first line of claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 3 recites the phrase "the γ -subunit" in second line of claim 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Sode (WO/2002/36779, published 10 May 2002).

Claim 1 is directed to an *Escherichia* bacterium, comprising DNAs encoding the α -subunit and the β -subunit of glucose dehydrogenase of *Burkholderia cepiacia* in an expressible form, wherein the bacterium is further modified so that the expression of a ccm system is enhanced. Sode et al. teach DNA encoding α -subunit, β -subunit, and γ -subunit (WO/2002/36779 Translation, lines 512-513, 592-595 and 722-724) of glucose dehydrogenase of *Burkholderia cepiacia* (Translation, lines 530-531). Sode teaches, plasmids including pBR322, pUC18, and pUC19 are suitable for expression of glucose dehydrogenase subunit genes in the host bacteria, *Escherichia coli* (Translation, lines 623-624). Intrinsically, Sode teaches constitutive expression of the glucose dehydrogenase, as suggested by the ability of Sode to produce the glucose dehydrogenase complex by merely culturing the transformed bacteria (Translation, lines 20-23). There is no mention of inducible promoters, so the examiner interprets the Sode reference as having constitutive expression of the glucose dehydrogenase subunits. According to the instant specification, the phrase “enhance the expression of

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the ccm system" is defined to mean recombinant glucose dehydrogenase genes constitutively expressed in *Escherichia* (Specification, page 9, parag.2).

Claim 2 is directed to the *Escherichia* bacterium according to claim 1, wherein the DNA encoding the α -subunit is located upstream from the DNA encoding the β -subunit, and expression of the subunits is regulated by a single promoter. Sode teaches, expression plasmids comprising nucleic acid sequences wherein the alpha subunit is upstream of the beta subunit (lines 723-724).

Claims 3-4 are directed to the *Escherichia* bacterium according to claim 1, wherein the DNA encoding the γ -subunit is located upstream from the DNA encoding the α -subunit. Sode teaches, transformants comprising expression plasmids wherein the nucleic acid sequence for the gamma subunit is upstream of the alpha subunit (lines 1230-1233).

Claim 5 is directed to the *Escherichia* bacterium according to claim 1, wherein the *Escherichia* bacterium is *Escherichia coli*. Sode teaches transformation of *E. coli* with the plasmids comprising α -subunit, β -subunit, and γ -subunit of GDH.

Claim 6 is directed to a method for producing a glucose dehydrogenase complex, which comprises culturing the *Escherichia* bacterium according to claim 1 so that the DNAs encoding the α -subunit and the β -subunit are expressed and the glucose dehydrogenase complex is produced, and collecting the complex. Sode teaches, "The manufacture procedure of the glucose dehydrogenase characterized by belonging to *Burkholderia cepacia*, cultivating to a medium the microbe which has the capability to

produce glucose dehydrogenase, and extracting glucose dehydrogenase from this medium or/and said microbe cell." (Translation, lines 20-23).

Therefore, the instant claims are anticipated by Sode.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sode (WO/2002/36779, published 10 May 2002) in view of Herbaud et al. (Biochim. Biophys

Acta. 2000; Vol.1481(1): 18-24) as evidenced by Arslan et al. (Biochem. Biophys. Res. Commun. 251 (1998) 744-747).

Claim 7 is directed to the *Escherichia* bacterium according to claim 1, wherein the bacterium is modified so that the expression of the ccm system is enhanced by the bacterium, comprising a plasmid comprising genes of a ccm operon operably linked to a promoter.

Claim 8 is directed to the *Escherichia* bacterium according to claim 7, wherein the plasmid is pEC86.

The teachings of Sode are described above in the 35 USC 102 section. Sode. does not teach the specific plasmid,

Herbaud et al. teach *E. coli* transformed with "pEC86 that contains the ccm genes" (page 19, col.2), in particular, those encoding α -subunit, β -subunit, and γ -subunit. Herbaud also teach "when the ccm genes are provided on a plasmid together with the structural gene for a mono- and a diheme c-type cytochrome, the cytochrome maturation occurs and seems to be increased" (page 18, col.2).

Claim 9 is directed to the *Escherichia* bacterium according to claim 1, wherein the bacterium is modified so that the expression of the ccm system is enhanced by replacing the bacterium's ccm operon promoter with another promoter. Herbaud teaches the plasmid, pEC86. Herbaud et al. (page 19, Materials and Methods, section 2.1) indicate that Arslan et al. describe in greater detail the structure of pEC86. Arslan et al. teach, "Overproduction of c-type cytochromes with pEC86 encoding the *ccm* genes." (page 745, col.1, Results). Arslan et al. further teach, "Plasmid pEC86 is

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derived from the vector pACYC184 and contains the *ccm* genes downstream of the *tet* promoter." (page 745, col.2). In addition, Arslan et al. teach, "Plasmid pEC86 provides a tool for constitutive *ccm* gene expression and in particular facilitates aerobic cytochrome c maturation. It can also be used to increase the amounts of endogenous c-type cytochromes." (page 747, col.1).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to utilize the specific plasmid, pEC86, as taught by Herbaud et al. with the invention of Sode.

The person of ordinary skill in the art would have been motivated to modify the teachings of Sode in with the teachings of Herbaud et al. because "when the *ccm* genes are provided on a plasmid together with the structural gene for a mono- and a diheme c-type cytochrome, the cytochrome maturation occurs and seems to be increased" (Herbaud et al., page 18, col.2).

The skilled artisan would have had a reasonable expectation of success in combining the teachings of Sode and Herbaud et al. because each of these teachings generated enhancement of the *ccm* system.

Therefore the method as taught by Sode in view of Herbaud et al. and as evidenced by Arslan et al. would have been *prima facie* obvious over the method of the instant application.

Conclusion

No claims are allowed.

Examiner Contact Information

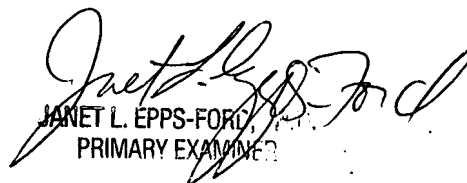
Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**.

The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott Long
Patent Examiner
Art Unit 1633


JANET L. EPPS-FORD
PRIMARY EXAMINER